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510(k) Summary

Hemo-Cath®
Summary of Safety and Effectiveness
Prepared November 22, 2011

Attachment 8

General Information

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 Phone: (215) 256-4201 Fax: (215) 256-9191
Contact:	Jean Callow Regulatory Specialist
Device Trade Name:	Hemo-Cath®
Common Name:	Hemodialysis Catheter, Implanted
Classification Name:	MSD – Blood access device and accessories
CFR Reference:	21 CFG 876.5540, Class III
Classification Panel:	Gastroenterology / Urology

Predicate Devices:

Device Trade Name:	Hemo-Cath®
Common Name:	Hemodialysis Catheter, Implanted
Classification Name:	LJF –Blood access device and accessories
CFR Reference:	21 CFR 876.5540, Class III
Classification Panel:	Gastroenterology / Urology
Premarket Notification:	K893439, concurrence date June 13, 1989 K091953, concurrence date September 16, 2009 K981125, concurrence date February 26, 1999 K030270, concurrence date April 14, 2003 K010306, concurrence date October 3, 2001

Performance Standards: Performance standards have not been established by FDA under section 514 of the Federal Food, Drug, and Cosmetic Act.

Indications for Use:

Medcomp's Hemo-Cath® silicone double lumen catheter can be utilitized for long term implantation as well as temporary access for hemodialysis, hemoperfusion, or apheresis therapy.

It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient.

Alternative insertion sites include subclavian vein as required.

Device Description:

- 12.5French double lumen design with cuff for long-term implant.
- Variety of lumen lengths: 15cm, 18cm, 24cm, 28cm, 32cm and 40cm.
- 12.5F with a pre-curved lumen in a 28cm and 32cm length.
- Radiopaque silicone material
- Lumen is connected to the extension via a soft pliable hub with a suture wing
- Red and blue clamps and red and blue luers are provided on the extension tube to prevent air/fluid communications
- The hub contains the device name and French size, clamp I.D. Rings are printed with the priming volume.

Safety and Performance Tests

Biocompatibility requirements of ISO 10993 *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing* for externally communicating, blood contacting, long-term devices were met. All materials used in the manufacture of the Hemo-Cath were previously cleared for similar applications by Medcomp, Inc.

Performance testing of the Hemo-Cath was conducted in accordance with the following international standards:

- *ISO 10555-1: 1997, Sterile Single Use-Intravascular Catheters, General Requirements*
- *ISO 10555-3: 1997, Sterile Single Use-Intravascular Catheters, Central Venous Catheters*
- *ISO 594-2: Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment – Part 2: Lock Fittings*

Subject product testing has yielded acceptable safety and performance outcomes.

Testing performed:
Air Leakage
Liquid Leakage
Priming Volume
Flow verse Pressure
Force at Break
Recirculation
Chemical Exposure
Accelerated Aging
Mechanical Hemolysis

The results of these tests, in conjunction with the substantial equivalence claims effectively demonstrate that the Split Cath® III is substantially equivalent to the cited predicate devices.

Summary of Substantial Equivalence

Based on the indications for use and safety and performance testing, the Hemo-Cath meets the requirements that are considered for its intended use and is substantially equivalent in design materials, sterilization, and indications for use to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Jean Callow
Regulatory Specialist
MEDCOMP (MEDICAL COMPONENTS)
1499 Delp Drive
HARLEYSVILLE PA 19438

MAR - 9 2012

Re: K113487
Trade/Device Name: Hemo-Cath®
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: February 7, 2012
Received: February 8, 2012

Dear Ms. Callow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807);

labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains 5cc Lidocaine: HCL 1% , which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing This drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113487

Device Name: ___ Hemo-Cath®_____

Indications for Use:

Medcomp's Hemo-Cath® silicone double lumen catheter can be utilitized for long term implantation as well as temporary access for hemodialysis, hemoperfusion, or apheresis therapy.

It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient.

Alternative insertion sites include subclavian vein as required.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113487